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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,571	09/04/2003	John A. Sazy	101896-706 (DEP-128CON)	6429
21125 7590 11/20/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	
			NOTIFICATION DATE	DELIVERY MODE
			11/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary

Application No.

10/655,571

Applicant(s)

SAZY, JOHN A.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6 and 10-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6 and 10-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,3,5,6,13,14,19,28,30 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schafer et al. (6143032). Fig. 3 shows a unitary body that is banana-shaped as viewed from above. Fig.2 illustrates the body has openings evenly spaced about the circumference. Schafer discloses the body has a continuous front arc and a continuous back arc with two radiuses of curvature either equal or different, col. 2, lines 26-32. Schafer also discloses the implant body can be made of a metal or polymer, col. 3, lines 14,15. According to Figs. 1 and 3, it can be construed that the width is greater than the length. Regarding Claim 30 is also rejected in the alternative, under 35 U.S.C. 103(a) as obvious over Schafer et al. It would have been obvious to one of ordinary skill in the art to modify the ratio of length to width to have a width at least 2.4 times greater the length for Schafer's implant since such a modification only involves routine skill in the art and would be considered by surgeons as they treat patients of various sizes, for example children would have smaller dimensions as opposed to adults requiring a much larger cage.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Harms et al. '305. Schafer et al. is explained supra. However, Schafer fails to teach the openings are parallelograms or rhombuses. Harms et al. show (Fig. 4) rhombus or parallelogram shaped openings (col. 2, lines 15,16) which allow bone cement to be placed through the openings. It would have been obvious to one of ordinary skill in the art to modify the shape of the openings and use parallelograms or rhombuses as taught by Harms with the implant of Schafer such that they provide a greater surface area to bond to.

Claims 15-18,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Dove et al. '261. Schafer et al. is explained supra. However, Schafer et al. fail to disclose the types of metals or polymers for the prosthesis is made from a carbon-fiber reinforced plastic or a resorbable polymer or stainless steel. Dove et al. teach that the spinal implant can be made from a variety of materials, such as carbon fiber reinforced polymers or stainless steel or biodegradable material, col. 1, lines 46-51. It would have been obvious to one of ordinary skill in the art to use alternative materials as taught by Dove et al. for the implant of Schafer et al. such that it can provide a lighter implant or a more radiopaque implant or one that degrades as tissue ingrowth occurs.

Claims 24,25,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Michelson (6302914). Schafer et al. is explained above. However, Schafer et al. fail to disclose the implant's width or length. Michelson (Fig. 18) shows a spinal cage for supporting the vertebrae. Michelson also teaches that the height and width of the implant correspond to the area that a disc may have been removed, col. 7, lines 47-56. It would have been obvious to one of ordinary skill in the art to use an implant with a width falling within the range of 24-28mm and a length of about 10mm as taught by Michelson for the implant of Schafer et al. such that it can provide the proper dimensions of the patients intervertebral space and support adjacent vertebrae.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Dove et al. '261 as applied to claim 20 above, and further in view of MacMillan et al. (5062850). Schafer et al. in view of Dove et al. is explained supra. However, Schafer as modified by Dove fail to disclose the use of polyglycolic acid for the spinal support device. MacMillan et al. teach the use of polyglycolic acid for the vertebral prosthesis because it slowly degrades, col. 6, lines 5-10. It would have been obvious to one of ordinary skill in the art to use polyglycolic acid as the implant material as taught by MacMillan et al. for the vertebral implant of Schafer et al. as modified by Dove et al. such that it degrades slowly to provide space for bone ingrowth.

Claims 22,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Preissman (6231615). Schafer et al. is explained supra. However, Schafer fails to disclose the use of an antibiotic with the polymer or plastic.

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Preissman teaches the use of injectable PMMA and the use of an antibiotic, col. 4, lines 2-10. Preissman also teaches the injectable PMMA is used in treating pain in vertebral compression fractures, col. 3, lines 65-67. It would have been obvious to one of ordinary skill in the art to inject polymethylmethacrylate with an antibiotic as taught by Preissman with the vertebral implant of Schafer et al. such that it enhances the treatment given to the patient to reduce infection and provides an efficient way to deliver a cement to aid in fixation and an antibiotic to the treatment site.

Claims 26, 27, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of McKay '449. Schafer et al. is explained supra. However, Schafer fails to teach the height to be about 10mm or the thickness of front arc of the implant to be about 1.5-2mm or the upper and lower edges of the implant formed with smoothly-sloping surfaces in a serpentine arrangement. McKay teaches (Fig. 3) a mesh type implant with the upper and lower surfaces having smoothly-sloping serpentine structure for engagement with the vertebrae. McKay additionally teaches that the serpentine upper and lower edges are for attaching or affixing to the vertebrae, col. 6, lines 24, 25. McKay teaches (Fig. 5) a spinal implant and that the thickness of a front arc can be "about 1mm". McKay also teaches (col. 6, lines 38-40, 53, 54) the thickness is sufficient to support the vertebrae and not break. The Examiner is interpreting "about 1.5mm" to be "about 1mm". It would have been obvious to one of ordinary skill in the art to use a thickness for the arc of the implant of "about 1.5mm" as taught by McKay for the implant of Schafer such that it provides a durable support for the vertebrae that can withstand compressible loads. McKay also teaches the height of the implant to be

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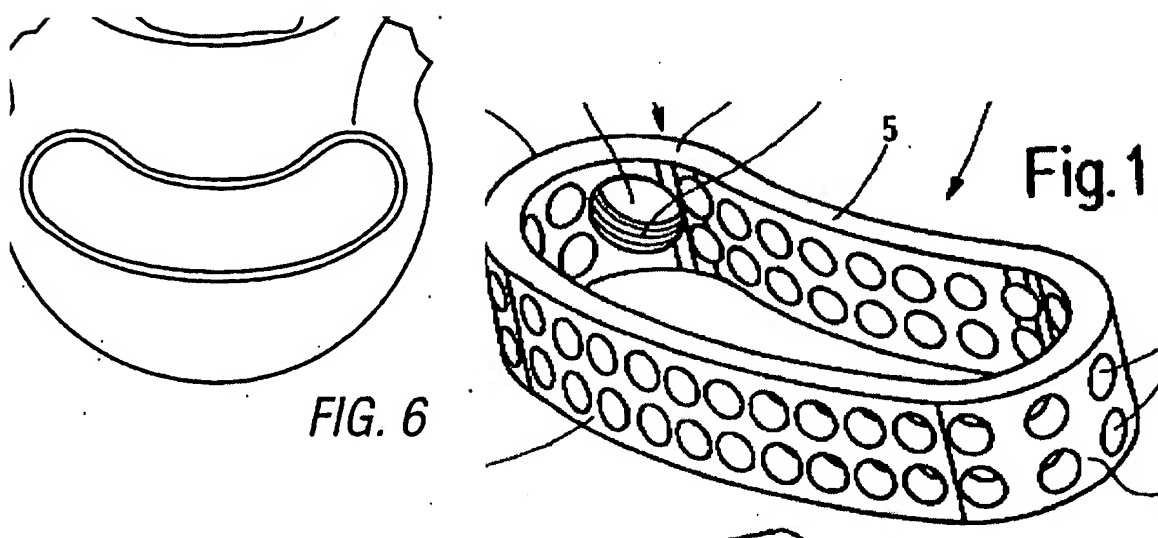
10mm, col. 6, line 36. It would have been obvious to one of ordinary skill in the art to use the teaching of providing a spinal cage with a height of 10mm as taught by McKay for the implant of Schafer such that it provides enough space between the vertebrae and approximates the natural disc space, col. 2, lines 62,63 of McKay. The use of a serpentine arrangement for affixing the implant to the vertebrae is well known in the art and would have been obvious to one of ordinary skill to incorporate the smoothly-sloping serpentine arrangement as taught by McKay with the cage of Schafer such that the implant does not move between the vertebrae once implanted.

Response to Arguments

Applicant's arguments filed 9/4/07 have been fully considered but they are not persuasive. Applicant argues that the spinal prosthesis disclosed by Schafer et al. is not banana-shaped, but kidney shaped. First the Examiner would like to point out that all bananas are not the same shape since there are numerous types of bananas that vary in size, shape and color. There are dwarf and red bananas that are short. Then there are Cavendish bananas that are longer and yellow. Then there is the plantain banana that is long and greenish with a more elongate appearance and less of curved look to them than the yellow Cavendish type. Thus, there is not an exact or specific shape that is implied, just because Applicant's claim recites "banana-shaped". Applicant also alleges the Schafer device looks like a cage similar to a device invented by Harms which the Applicant says is kidney-shaped and not banana-shaped. Comparing the

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prior art with other prior art is irrelevant and thus the Examiner would like to illustrate a comparison of Applicant's device with that of Schafer's as shown below.



The figure on the left is the claimed invention and the figure on the right is the prior art device disclosed by Schafer. One of ordinary skill would clearly state they look identical. Applicant also argues the Examiner has not shown where the different radius of curvature is disclosed. However, it appears the Applicant's representative has totally ignored or overlooked that the Examiner referred to col. 2, lines 29-31 in the office action where two different radii are disclosed by Schafer. Applicant again compares the prior art device of Harms with the prior art Schafer implant in addressing the rejection of claim 30 made by the Examiner. The Examiner would like to note that a comparison of prior art not relied on is a moot point and the Examiner will not entertain these issues.

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Applicant argues that the dimensions of Schafer's device cannot be modified as claimed. However, clearly one of ordinary skill in the art is capable of modifying an implant's size to accommodate the different anatomical dimensions found in patients.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on Monday-Friday from 8:30am to 5pm. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

Brian Pellegrino

**BRIAN E. PELLEGRINO
PRIMARY EXAMINER**